FISCAL IMPACT STATEMENT ON BILL NO. **\$477**

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TO: The Honorable Harvey S. Peeler, Chairman, Senate Medical Affairs Committee

FROM: Office of State Budget, Budget and Control Board

ANALYSTS: Allan Kincaid, Kate Billing and Bryce Wilson

DATE: April 4, 2005 SBD: 2005340

AUTHOR: Senator Reese PRIMARY CODE CITE: 44-7-65

SUBJECT: Registration of Clinical Trials by Hospitals or Universities

ESTIMATED FISCAL IMPACT ON GENERAL FUND EXPENDITURES:

A Cost to the General Fund (See Below)

ESTIMATED FISCAL IMPACT ON FEDERAL & OTHER FUND EXPENDITURES: See Below

BILL SUMMARY:

The Bill would amend section 44-7-65 so as to provide that a hospital or university that receives state funding must not conduct clinical trials unless these trials are registered with the Office of Research and Statistics of the State Budget and Control Board and the trial results are reported to the Office and made available to the public.

EXPLANATION OF IMPACT:

State Budget and Control Board (Board)

The Board staff indicates there will be recurring costs of \$60,924 with one new position and non-recurring costs of \$116,859. The non-recurring costs are for developing a secure web-site to provide the information to the public.

University of South Carolina School of Medicine

The USC School of Medicine indicates that the direct impact associated with administrative reporting to be minimal. However, enactment could deter companies from conducting clinical trials and ultimately impact agency revenue.

Medical University of South Carolina (MUSC)

MUSC conducts numerous corporately funded clinical trials each year. MUSC indicates if the registration process results in studies being delayed this could reduce the number of trials being conducted and ultimately impact agency revenue.

Department of Health and Human Services

Enactment would have no impact on the General Fund of the State, or on Federal and/or Other Funds.

Department of Mental Health

DMH indicates that as long as the registration can be accomplished with the Office of Research and Statistics relatively quickly and easily, there should be no fiscal impact to the agency.

Approved by:

Don Addy

Assistant Director, Office of State Budget